Treatment of varicose veins by endovenous laser therapy: assessment of results by ultrasound surveillance

Kenneth Myers, Robert Fris and Damien Jolley

ABSTRACT

Objective: To assess the efficacy of endovenous laser therapy (EVLT) for treating varicose veins with saphenous reflux.

Design: A trial of treatment, with results assessed by ultrasound surveillance.

Setting: Outpatient clinics with sonographer and nursing support.

Main outcome measures: Control of reflux; occlusion or obliteration of the saphenous veins assessed by ultrasound.

Results: EVLT was used to treat 404 veins in 308 patients. Univariate life table analysis showed primary success in 80% (95% CI, 69%–87%) and secondary success after further treatment of recurrent saphenous vein reflux by ultrasound-guided sclerotherapy in 88% (95% CI, 78%–95%) at 3 years. On multivariate Cox regression analysis, none of the covariates studied were associated with ultrasound failure.

Conclusions: Early results indicate that EVLT effectively controlled saphenous reflux. Its advantages are that it is performed as an outpatient procedure under local anaesthesia with immediate mobilisation, causes minimal disruption of activities, and avoids surgical trauma.

MJA 2006; 185: 199–202

Conventional treatment of saphenous vein reflux by surgical ligation or stripping leads to appreciable trauma, disruption of activities, scarring and high late recurrence rates.[1] Alternative, non-surgical techniques are gaining increasing acceptance. Endovenous laser therapy (EVLT) provides a percutaneous technique to destroy larger diameter saphenous veins as an outpatient procedure under local anaesthesia, with minimal disruption of activities and no surgical trauma.[2-5] In this article, we describe our early results for 404 saphenous veins in 308 patients treated by EVLT and followed up by ultrasound surveillance.

METHODS

Two of us who are surgeons used essentially identical techniques for EVLT. The procedure was introduced in January 2002 by K M and adopted in November 2002 by R F, and follow-up for analysis continued until August 2005. Median times for each surgeon's experience were 31 months for K M and 22 months for R F.

Approval was obtained from the Epworth Hospital ethics committee for endovenous treatment of varicose veins.

Patients and veins treated

EVLT was offered to patients where preliminary ultrasound scanning showed great or small saphenous reflux with a straight section of saphenous vein of diameter greater than 5–6 mm (30% of all patients referred with varicose veins). Most of the remainder were treated by ultrasound-guided sclerotherapy, as few patients elected to be treated by surgery.

There were 308 patients treated for varicose veins with saphenous reflux (K M, 190; R F, 118), consisting of 189 women (61%) and 119 men, with an age range from 15 to 89 years (median, 52 years). Great and small saphenous veins of the same limb were treated at the one procedure in eight patients and saphenous veins from each limb were treated in 88 patients, initially as separate procedures, but then always at the one session. In total, 404 saphenous veins (334 great; 70 small) were treated in 396 limbs.

The clinical, aetiological, anatomical, and pathophysiological (CEAP) classification was used to assess the limbs.[6] There were 361 limbs with uncomplicated varicose veins (C2–3, 91%) and 35 limbs with complications (C4–6), due to lipodermatosclerosis ($n = 26$), healed past venous ulceration ($n = 6$) or active ulceration ($n = 3$). Primary disease was present in all limbs, and none had features of the post-thrombotic syndrome. There was persistent or recurrent reflux after past saphenous vein surgery by other surgeons in 20 limbs (15 for great saphenous and 5 for small saphenous disease).

Duplex scanning performed by specialist vascular sonographers linked to the surgical units was used to select saphenous veins suitable for EVLT. Limbs were evaluated to detect superficial, deep and perforator reflux, mark the site and extent of disease, and measure the length and diameters of refluxing saphenous veins as previously described.[7] All limbs treated had reflux through the corresponding saphenous junction or other major connections to deep veins. The lengths of veins treated ranged from 5 to 55 cm (median, 34 cm) and their diameters from 5 to 20 mm (median, 8 mm).

Technique for EVLT

EVLT was performed using the Diomed 810 nm diode system (Diomed, Inc, Andover, Mass, USA). It is not necessary to sedate the patient. Ultrasound guides the various stages using a 12–5 MHz linear array probe for most limbs. The distal end of the saphenous vein to be treated and the saphenofemoral or saphenopopliteal junction are marked. The limb is prepared as for a surgical operation and the operator is gowned and gloved.

The ultrasound probe in a sterile sheath shows the vein in a longitudinal view. The puncture site is infiltrated with 1% plain xylocaine, a stab is made to accommodate a sheath, a 19-gauge angiogram needle punctures the vein under vision, a 0.035-inch safety-J guide wire is passed up the vein to the saphenous junction, and a 45-cm-long 5F sheath is passed over the wire to the junction. Ultrasound is used to guide injection of 7–8-mL aliquots of a 0.2% xylocaine with adrenaline solution through a 25-gauge needle into the fascial space surrounding the vein at intervals down its length. The fluid compresses the vein onto the probe and acts as a heat sink for laser energy, protecting adjacent structures as well as providing anaesthesia.

The guidewire and sheath dilator are removed, and a laser probe is passed up the sheath. Markers on the probe allow 2 cm of probe to extend beyond the sheath. Settings are selected to deliver 14 W of power at a continuous rate. The probe tip is placed

2 cm below either saphenous junction and the position of the probe below the junction is confirmed by transillumination. The probe is then activated and withdrawn at about 3 mm/s (a faster rate was used early in the study).

After completion of EVLT, the limb is placed in firm compression bandages and the patient is immediately ambulated. Pain is usually well controlled by oral analgesics, and most patients are able to resume normal activities by the next day.

Further treatment by ultrasound-guided sclerotherapy for residual distal veins was required after 80% of procedures, usually performed 1–3 weeks after EVLT, to control tributaries (70%) and the distal saphenous vein (10%). No surgical procedure has been required in any limb.

Ultrasound surveillance

It is essential to repeat the ultrasound scan at 3–5 days after the procedure to confirm that the treated vein has been occluded, determine residual veins to be treated, and exclude deep vein thrombosis. It is then desirable to repeat the scan at 6 weeks, then 6-monthly for 2 years, then annually, looking for occlusion or obliteration, or for recanalisation of the vein.

Statistical analysis

Follow-up with serial ultrasound scans at the above intervals was used for survival analysis.[8] Success was defined as continuing occlusion or obliteration without reflux in any segment of treated vein, as determined by ultrasound.

Primary failure occurred if there was persistent or recurrent saphenous vein reflux at any time during follow-up, and was defined as failure to occlude the lumen, or recanalisation with reflux in a part or all of the treated saphenous vein, whether or not this was associated with clinical persistence or recurrence of varicose veins.

Secondary failure was defined as failure to occlude the lumen, or recanalisation and reflux after primary failure, either because of a decision for no further treatment or if further treatment by ultrasound-guided sclerotherapy was unsuccessful.

Data were progressively censored if veins remained occluded at the patient's last study visit. The number of veins available for review at various intervals through the study (as patients were seen at the most recent visit, were lost to follow-up or died) are shown in the figures.

Univariate Kaplan–Meier life table analysis was used to calculate primary and secondary ultrasound success and failure rates.[8] The time to failure was the difference between the date of EVLT and the date that recurrent reflux was demonstrated at follow-up scans. All patients presented for the first post-procedure scan at day 3–7; if failure was noted at this scan, then this was used as the failure date for survival analysis, although it is probable that the procedure had failed from the time it was performed. If a patient noted to have recurrent saphenous reflux had missed a previous scheduled visit, then failure due to recurrent saphenous reflux was dated back to the time of that missed visit.

Multivariate Cox regression proportional hazard analysis was used to correlate success or failure independently with various covariates relating to the patients, limbs and treated veins. These were age, sex, side, clinical CEAP category (C2–3 v C4–6), treating surgeon (KM or RF), vein treated (great or small saphenous), primary disease without previous treatment or recurrence after previous surgery, time to the date of procedure from the date for commencement of each surgeon's experience (days), length of vein treated (centimetres), representative diameter of the vein (millimetres), and rate of withdrawal of the laser probe (millimetres per second).

To avoid linearity assumptions, we categorized continuous predictor variables (age, surgeon experience, length of vein, diameter of vein, and rate of withdrawal). We selected categories based on quartiles of the variable's distribution, independently of its association with the outcome variable. We used a likelihood-ratio χ^2 test to assess the contribution of each predictor variable in a final model.

The unit of analysis for Cox proportional hazard regression was the vein. We used the Huber–White sandwich estimator of variance to accommodate clustering of veins within the same patient. Each vein inherited the higher-level characteristics of its "parent" limb and patient within the regression model.

Statistical analysis was performed using Stata Statistical Software, release 9 (StataCorp, College Station, Tex, USA).

RESULTS

Initial technical success was achieved in 401 of 404 procedures. In one limb treated for small saphenous reflux, the guidewire and then the laser probe passed up outside the vein without this being recognised until after the procedure. In two other limbs treated for great saphenous reflux, it was considered that a large vein had not been adequately compressed onto the laser probe to achieve occlusion.

In 21 limbs, recanalisation was detected on surveillance, usually to a minor degree when compared with the initial reflux. This resulted in a primary ultrasound success rate at 3 years by life table analysis of 80% (95% CI, 69%–87%) (Box 1A). Eleven of these limbs were treated by ultrasound-guided sclerotherapy to obliterate the recurrent vein at intervals from 7 to 570 days after EVLT, and this was successful in all but one, resulting in a secondary ultrasound success rate at 3 years by life table analysis of 88% (95%,CI, 78%–95%) (Box 1B).

None of the covariates studied were associated with late failures on Cox regression analysis (data available from authors).

Ultrasound detected 14 of 334 limbs (4.2%) treated for great saphenous reflux where reflux later developed into thigh tributaries from the saphenofemoral junction ($n = 12$) or low abdominal or pelvic veins ($n = 2$).

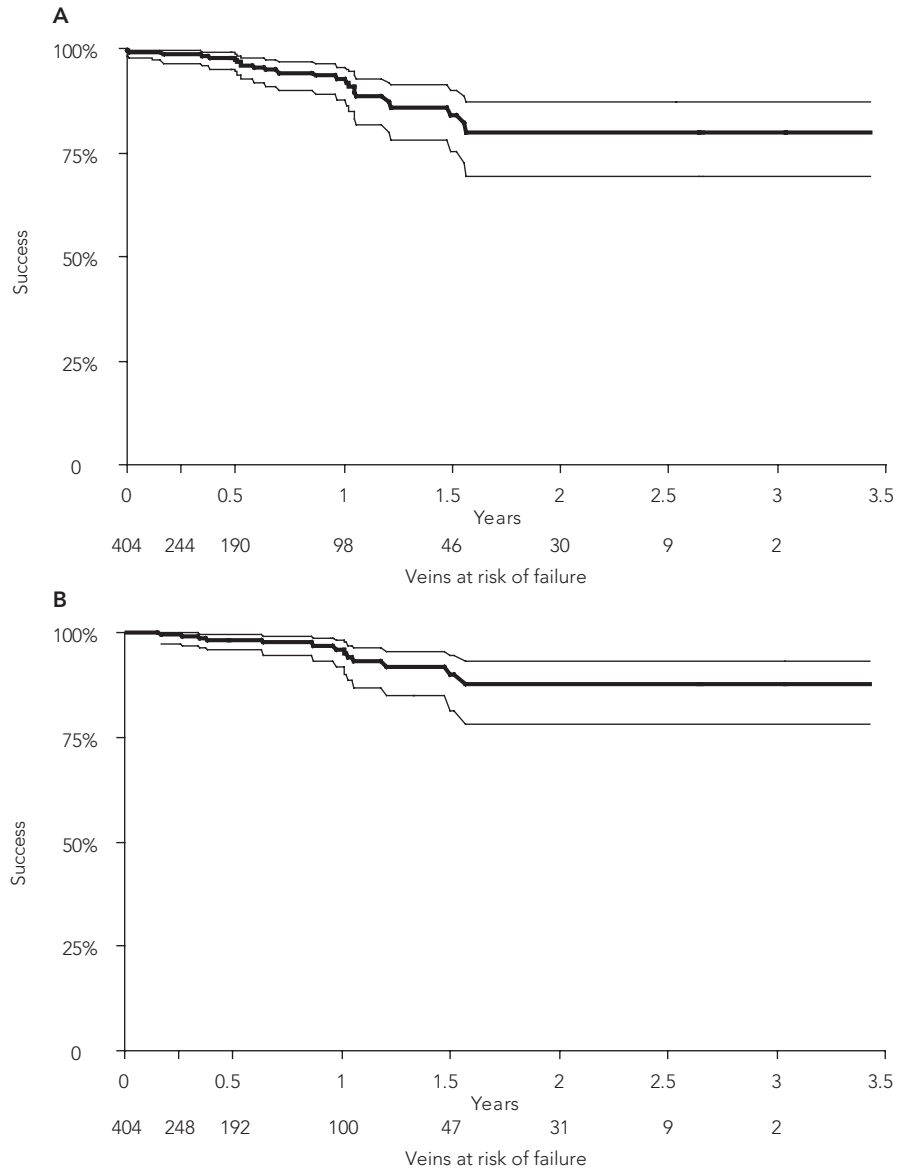
Complications

Patients are warned about vein thickening and tenderness along tributaries treated by ultrasound-guided sclerotherapy after EVLT, and are told that these will completely resolve in time.

One patient with very severe right heart failure and high venous pressures causing intermittent bleeding from varices developed severe painful inflammatory swelling along the treated great saphenous vein; this was the only patient in the series who subsequently died, at 18 months from the cardiac disease. Otherwise, all patients had temporary mild pain that was controlled by oral analgesics with no more than moderate bruising along the site.

Partial thrombosis of the popliteal vein was detected in two limbs: just above the saphenopopliteal junction after small saphenous EVLT in one limb, and in the distal popliteal vein after ultrasound-guided sclerotherapy for tributaries at 2 weeks after great saphenous EVLT in the other. Serial scans showed that these progressively incorporated into the wall over 3 weeks. Another four limbs developed posterior tibial vein occlusion after ultrasound-guided sclerotherapy for tributaries, and serial scans showed that each recanalised over about 3 weeks. These were all asymptomatic, and were only detected because of routine postoperative scanning.

1 Kaplan–Meier life table analysis of success rates after endovenous laser therapy for all veins treated



A: Primary success rates. **B:** Secondary success rates. The numbers along the lower axis represent the numbers of veins available for analysis at intervals through the study. Thin lines represent 95% confidence intervals. ◆

Another patient developed clinical pulmonary embolism (confirmed by computed tomography) at 3 days after EVLT; no deep vein thrombosis was identified and no long-term sequelae occurred. Thus, the incidence of thromboembolic complications in the 308 patients was 2.2%.

One patient developed sural nerve palsy after small saphenous EVLT, with partial recovery at 6 months. There were no other nerve injuries or thermal damage.

No other significant complications were encountered.

DISCUSSION

We found that a single episode of EVLT effectively controlled saphenous vein reflux in 80% of veins. EVLT is equally suited to young patients requiring the best cosmetic outcome and elderly patients with complications who might be high risk for surgery. Perivenous anaesthesia allows veins of any diameter or length to be treated by EVLT, but it is probably necessary to ensure that large diameter veins are adequately compressed.

Thromboembolic complications can occur with any treatment for varicose veins. In this series, EVLT had a 2.2% incidence of thromboembolic complications. Van Rij and colleagues documented deep vein thrombosis in 5.3% of limbs after varicose vein surgery, although most were localised to the tibial veins.[9]

In the setting of clinical practices, it was not possible to ensure complete follow-up of every patient, but most attended for review, understanding the potential high incidence of recurrence of varicose disease after any form of treatment.

EVLT damages a blood-filled vessel by steam formation, leading to endothelial denudation, collagen contraction and vein wall fibrosis,[10-13] and in many limbs the vein is no longer visible at the 6–12 month scans. Our results are similar to those in another large series.[2] Other studies have reported satisfactory results for the great saphenous[3,4] and small saphenous veins.[5]

An alternative technique using thermal ablation from a radiofrequency probe has also produced good results with low complication rates.[14-17] Ultrasound surveillance shows occlusion of most saphenous veins and infrequent development of new veins in the groin with this technique.[16] Randomised trials of radiofrequency closure versus surgery found significantly less postoperative pain, faster rehabilitation, lower cost and persisting better quality of life, as well as similar control of the veins.[14-17]

Outcomes are satisfactory for treatment of saphenous reflux by ultrasound-guided sclerotherapy,[18-20] but there is insufficient information to determine the efficacy of ultrasound-guided sclerotherapy for larger saphenous veins.

Ultrasound surveillance detects a high incidence of failure after surgery for varicose veins.[1] Van Rij and colleagues found 25% recurrence after great saphenous surgery and 50% recurrence after small saphenous surgery at 3 years.[21] A Swedish study of outcome 10 years after great saphenous ligation and stripping found that 86 of 100 limbs had recurrence involving segments of the great saphenous veins.[22] Ultrasound studies after small saphenous surgery found that only 39% of 59 operations were successful at early follow-up in a British report,[23] and 5 of 28 operations were successful at 3 months in a Dutch study.[24] A British review suggests that this may be due to reluctance to strip the small saphenous vein because of fear of nerve injury.[25]

There is a high incidence of reconnection from the common femoral vein or low

abdominal or pelvic veins to thigh tributaries after surgery, due to opening of pre-existing veins.[26,27] Traditional teaching is to ligate all tributaries at the saphenofemoral junction, but there is growing concern that this might predispose to reconnections into thigh veins rather than normal drainage through the saphenous junction. Endovenous techniques are not associated with a high incidence of recurrence in the groin,[28] suggesting that leaving tributaries from above the groin may be an advantage.

Varicose veins are an extremely common problem in the community. Their treatment places a considerable strain on the medical system, with long waiting times for operation in the public hospital system. Endovenous procedures allow more efficient management of large numbers of patients with outpatient treatment. EVLT is simple to perform, well accepted by patients, and relatively atraumatic and safe. Our study shows that EVLT is effective for dealing with varicose veins with saphenous reflux.

Patient satisfaction, clinical control of superficial varices, and cost–benefit studies are important outcomes, but were not assessed in this study. Longer follow-up is required to allow confidence of lasting success. Ideally, randomised trials comparing EVLT with surgery will be performed.

ACKNOWLEDGEMENTS

We thank our sonographers and nursing sister — Amy Clough, Jacqui Kirwan, Michelle Rodeh, Jane Chambers and Penny Koh in Melbourne, and Bronwyn Allen and Daryl Queenin in Auckland — for their invaluable assistance and advice.

COMPETING INTERESTS

None identified.

AUTHOR DETAILS

Kenneth Myers, MS, FRACS, FACS, Vascular Surgeon[1]
Robert Fris, FRACS, FACS, Vascular Surgeon[2]
Damien Jolley, MSc(Epidemiol), Senior Biostatistician[3]

1 Epworth Hospital, Melbourne, VIC.
2 Northern Vein Centre, Auckland, New Zealand.
3 Monash Institute of Health Services Research, Melbourne, VIC.

Correspondence: kamyers@bigpond.net.au

REFERENCES

1 Perrin MR, Guex JJ, Ruckley CV, et al. Recurrent varices after surgery (REVAS), a consensus document. REVAS group. *Cardiovasc Surg* 2000; 8: 233-245.
2 Min RJ, Khilnani N, Zimmet SE. Endovenous laser treatment of saphenous vein reflux: long-term results. *J Vasc Interv Radiol* 2003; 14: 991-996.
3 Proebstle TM, Gul D, Lehr HA, et al. Infrequent early recanalization of greater saphenous vein after endovenous laser treatment. *J Vasc Surg* 2003; 38: 511-516.
4 Timperman PE. Prospective evaluation of higher energy great saphenous vein endovenous laser treatment. *J Vasc Interv Radiol* 2005; 16: 791-794.
5 Proebstle TM, Gul D, Kargl A, Knop J. Endovenous laser treatment of the lesser saphenous vein with a 940-nm diode laser: early results. *Dermatol Surg* 2003; 29: 357-361.
6 Myers KA. Classification and grading of chronic venous disease in the lower limbs: a consensus statement. American Venous Forum. *Aust N Z J Surg* 1995; 65: 769-772.
7 Myers KA, Ziegenbein RW, Zeng GH, Matthews PG. Duplex ultrasonography scanning for chronic venous disease: patterns of venous reflux. *J Vasc Surg* 1995; 21: 605-612.
8 Lee ET. Statistical methods for survival data analysis. Belmont: Lifetime Learning Publications, 1980.
9 van Rij AM, Chai J, Hill GB, Christie RA. Incidence of deep vein thrombosis after varicose vein surgery. *Br J Surg* 2004; 91: 1582-1585.
10 Proebstle TM, Sandhofer M, Kargl A, et al. Thermal damage of the inner vein wall during endovenous laser treatment: key role of energy absorption by intravascular blood. *Dermatol Surg* 2002; 28: 596-600.
11 Proebstle TM, Lehr HA, Kargl A, et al. Endovenous treatment of the greater saphenous vein with a 940-nm diode laser: thrombotic occlusion after endoluminal thermal damage by laser-generated steam bubbles. *J Vasc Surg* 2002; 35: 729-736.
12 Min RJ, Khilnani NM. Endovenous laser treatment of saphenous vein reflux. *Tech Vasc Interv Radiol* 2003; 6: 125-131.
13 Proebstle TM, Krummenauer F, Gul D, Knop J. Nonocclusion and early reopening of the great saphenous vein after endovenous laser treatment is fluence dependent. *Dermatol Surg* 2004; 30: 174-178.
14 Rautio T, Ohinmaa A, Perala J, et al. Endovenous obliteration versus conventional stripping operation in the treatment of primary varicose veins: a randomized controlled trial with comparison of the costs. *J Vasc Surg* 2002; 35: 958-965.
15 Lurie F, Creton D, Eklof B, et al. Prospective randomized study of endovenous radiofrequency obliteration (closure procedure) versus ligation and stripping in a selected patient population (EVOLVeS Study). *J Vasc Surg* 2003; 38: 207-214.
16 Pichot O, Kabnick LS, Creton D, et al. Duplex ultrasound scan findings two years after great saphenous vein radiofrequency endovenous obliteration. *J Vasc Surg* 2004; 39: 189-195.
17 Lurie F, Creton D, Eklof B, et al. Prospective randomized study of endovenous radiofrequency obliteration (closure) versus ligation and vein stripping (EVOLVeS): two-year follow-up. *Eur J Vasc Endovasc Surg* 2005; 29: 67-73.
18 Kanter A, Thibault P. Saphenofemoral incompetence treated by ultrasound-guided sclerotherapy. *Dermatol Surg* 1996; 22: 648-652.
19 Belcaro G, Cesarone MR, Di Renzo A, et al. Foam-sclerotherapy, surgery, sclerotherapy, and combined treatment for varicose veins: a 10-year, prospective, randomized, controlled, trial (VEDICO trial). *Angiology* 2003; 54: 307-315.
20 Cabrera J, Cabrera J, Garcia-Olmedo MA. Treatment of varicose long saphenous veins with sclerosant in microfoam form: long-term outcomes. *Phlebology* 2000; 15: 19-23.
21 van Rij AM, Jiang P, Solomon C, et al. Recurrence after varicose vein surgery: a prospective long-term clinical study with duplex ultrasound scanning and air plethysmography. *J Vasc Surg* 2003; 38: 935-943.
22 Blomgren L, Johansson G, Dahlberg A, et al. Recurrent varicose veins: incidence, risk factors and groin anatomy. *Eur J Vasc Endovasc Surg* 2004; 27: 269-274.
23 Rashid HI, Ajeel A, Tyrrell MR. Persistent popliteal fossa reflux following saphenopopliteal disconnection. *Br J Surg* 2002; 89: 748-751.
24 Spronk S, Boelhouwer RU, Veen HF, den Hoed PT. Subfascial ligation of the incompetent short saphenous vein: technical success measured by duplex sonography. *J Vasc Nurs* 2003; 21: 92-95.
25 Winterborn RJ, Campbell WB, Heather BP, Earnshaw JJ. The management of short saphenous varicose veins: a survey of the members of the vascular surgical society of Great Britain and Ireland. *Eur J Vasc Endovasc Surg* 2004; 28: 400-403.
26 Myers KA, Zeng GH, Ziegenbein RW, Matthews PG. Duplex ultrasound scanning for chronic venous disease: recurrent varicose veins in the thigh after surgery to the long saphenous vein. *Phlebology* 1996; 11: 125-131.
27 El Wajeh Y, Giannoukas AD, Gulliford CJ, et al. Saphenofemoral venous channels associated with recurrent varicose veins are not neovascular. *Eur J Vasc Endovasc Surg* 2004; 28: 590-594.
28 Fassiadis N, Kianifard B, Holdstock JM, Whiteley MS. Ultrasound changes at the saphenofemoral junction and in the long saphenous vein during the first year after VNUS closure. *Int Angiol* 2002; 21: 272-274.

(Received 18 Apr 2005, accepted 20 May 2006) ❑